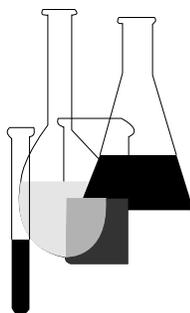




Product Properties Test Guidelines

OPPTS 830.6317 Storage Stability



INTRODUCTION

This guideline is one of a series of test guidelines that have been developed by the Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency for use in the testing of pesticides and toxic substances, and the development of test data that must be submitted to the Agency for review under Federal regulations.

The Office of Prevention, Pesticides and Toxic Substances (OPPTS) has developed this guideline through a process of harmonization that blended the testing guidance and requirements that existed in the Office of Pollution Prevention and Toxics (OPPT) and appeared in Title 40, Chapter I, Subchapter R of the Code of Federal Regulations (CFR), the Office of Pesticide Programs (OPP) which appeared in publications of the National Technical Information Service (NTIS) and the guidelines published by the Organization for Economic Cooperation and Development (OECD).

The purpose of harmonizing these guidelines into a single set of OPPTS guidelines is to minimize variations among the testing procedures that must be performed to meet the data requirements of the U. S. Environmental Protection Agency under the Toxic Substances Control Act (15 U.S.C. 2601) and the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136, *et seq.*).

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OPPTS 830.6317 Storage stability.

(a) **Scope**—(1) **Applicability.** This guideline is intended to meet testing requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136, *et seq.*).

(2) **Background.** The source material used in developing this harmonized OPPTS test guideline is OPP guideline 63–17 Storage stability (Pesticide Assessment Guidelines, Subdivision D: Product Chemistry, EPA Report 540/9–82–018, October 1982) and 40 CFR 158.190 Physical and chemical characteristics.

(b) **Test methods**—(1) **Objective.** (i) Data on the physical and chemical characteristics of pesticide products are used to confirm or provide supportive information on their identity. Such data are also used in reviewing the production or formulating process used to produce the pesticide or product.

(ii) The objective of this test is to determine how long the product will retain the percent active ingredient in its packaging material corresponding to its useful shelf life. The storage stability study provides data on change (or lack of change in product composition over time. If certain ingredients decompose, other new chemicals are formed whose toxicity and other characteristics must be considered.

(2) **Test details.** For storage stability, the Agency recommends the following test:

(i) The test should be conducted with the product in its commercial package or in smaller packages of the same construction and materials.

(ii) The concentration of the active ingredient in the product shall be determined at the beginning of the test period, after 3 months, after 6 months, and at the end of the test period. Deterioration or degradation of the product during the test period should be determined. At the end of the test period, the product should be examined for physical changes, such as phase separation or “clumping,” and, in particular, any changes which would interfere with the usefulness or safe handling of the product if used according to the label directions.

(iii) The overall test period shall be for at least 1 year. For pesticide products expected to be on the market or expected to be efficacious for longer than one year, it is recommended that the registrant consult with the Agency for test guidance.

(iv) The test shall be conducted under either of the following conditions:

(A) At 20 °C or 25 °C, and, if the package is permeable, at a relative humidity of 50 percent.

(B) Under warehouse conditions which reflect the expected storage conditions of the commercial product.

(C) The test parameters may be expanded to include accelerated conditions, such as elevated temperature (or 40 °C-54 °C) or cold temperature extremes (-20 °C-0 °C).

(v) The test substance should be quantitatively analyzed for active ingredient content and changes in impurities as a result of degradation or packaging deterioration over the test period. Results should be reported as concentration in weight percent.

(vi) The test substance and container should be observed for any physical changes at each test interval, recording all observations in the raw data. All test containers should be reweighed at each of the test intervals, prior to and after sampling, to monitor weight.

(vii) If an alternative method is used, it is recommended that the registrant consult with the Agency prior to adopting the test method.

(3) **Combined testing.** A study of the storage stability of a product may be performed in combination with the corrosion characteristics test described in OPPTS 830.6320.

(c) **Reporting.** (1) The report shall describe the duration of the test and the conditions under which the storage stability test was conducted (e.g., temperature, humidity).

(2) The report shall include quantitative analyses for the active ingredient at the initiation of the test and at each test interval. Any degradation or deterioration of the packaging shall also be recorded at the same test intervals.

(3) The report shall describe any physical changes in the product during the test period and also the consequences, if any, of such changes for safe handling and use of the product.

(4) Any methods used to characterize the physical properties of a pesticide be described in the application for registration and copies of such methods must be submitted with the application.

(5) The applicant shall submit his own statistical evaluation of the precision and accuracy of these measurements (e.g., standard deviations or confidence intervals) when appropriate.